UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,839	12/21/2001	Richard Derose	022650-685	4793

7590 11/29/2006

Norman H. Stepno
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER	
HELMER, GEORGIA L	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,839	DEROSE ET AL.	
	Examiner	Art Unit	
	Georgia Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *2-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/21/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Status of the Claims

1. The Office acknowledges receipt of Applicants' Response; dated 18 September 2006.

2. Claims 1-12 are pending, claims 2-12 have been withdrawn. Claim 1 is examined in the instant action.

3. This action is made FINAL.

4. This application contains claims 2-12 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

5. All rejections not addressed below have been withdrawn.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

7. Applicant traverses the restriction requirement saying primarily that claims 2-10 "are directed to methods which can only result in the production of a nucleic acid in which the recited intron is serving as a genetic regulatory element in a chimeric gene as recited in claim 1 or a chimeric gene within the scope of claim 12. Therefore it is difficult to image a search strategy for these claims that would be mutually exclusive in the search of claims 1, 11 and 12 or how there could possibly be serious burden imposed upon the Examiner in examining this relatively limited number of claims together". (Response, p. 6)

Applicant's traversal is unpersuasive. As set forth in the Office Action of 17 March 2006, the restriction requirement sets for that:

"Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as probing other plant genomes to assay for the presence of introns in native genes".

Clearly the product as claimed can be used in a materially different process such as probing other plant genomes to assay for the presence of introns in native genes. This is an entirely different use of the nucleic acid than that proposed in claim 12, for example. MPEP 806.05(h) clearly illustrates that restriction between products and processes of their use are clearly mandated, appropriate and reasonable. Furthermore, the non-elected claims required additional elements such as herbicide resistance coding sequences, multiple intron SEQ ID Nos., multiple signal peptides, and multiple promoters, each requiring a burdensome search not required by the elected group.

Applicant's traversal is unpersuasive.

Claim Rejections - 35 USC § 112-written description

8. Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in the Office Actions mailed 2 July 2004, 18 April 2005 and 17 March 2006.

Applicant traverses saying primarily (Response, p. 7) that the only basis on which the Examiner is maintaining the rejection is that Applicant has not defined the size or size range of the 5' region in which the expected 5' intron would occur. Applicant says that Sinibaldi demonstates that one of ordinary skill in the art knew how to recognize introns within genes. Applicant s further asserts that the specification and Chaubet teach that the first intron of a plant H3.3 gene can be found between the promoter sequence and the initiation codon of the gene.

Applicant's traversal is unpersuasive. Claim 1 is drawn to "[a]n isolated DNA sequence serving as a genetic regtulatory element in a chimeric gene, wherein said DNA sequence is the intron of the 5'non-translated region of a plant H3.3 histone gene". The two Arabidopsis genes taught in the specification are indicated to be "H3.3-like" variants. At no point are they called H3.3 genes. The relationship of "H3.3-like" genes to H3.3 genes is not set forth. Furthermore, the single species of "Arabidopsis" is not representative of the genus "plant".

Applicant traverses primarily that Chaubet et al teach that the polypeptide sequences identical to those encoded by the two Arabidopsis genes from which the two introns of Example 2 in the specification are derived have also been deduced from an alfalfa cDNA and a barley cDNA. Thus one of ordinary skill in the art would have known of additional plant H3.3 genes in other species.

Applicant's traversal is unpersuasive. The polypeptide sequences deduced from which the alfalfa cDNA and from the barley cDNA were not known to be the sequences of plant H3.3 genes. These sequences were, at best, putative H3.3-like gene sequences. Thus one of ordinary skill in the art would not have known of additional plant H3.3 genes as of the time of filing of the instant case.

Applicant traverses primarily that both the specification and Chaubet et al work teach that the first intron of a plant H3.3 gene can be found between the promoter sequence and the initiation codon of the gene. Thus the teaching of the specification combined with what was known in the art combine to provide a description of representative species of the intron, which serves as a genetic regulatory element of a chimeric gene in the claimed nucleic acid.

Applicant's traversal is unpersuasive. No information is given on the size of the DNA "between the promoter sequence and the initiation codon of the gene". In the case of the two genes taught in the specification, this distance is a short run of DNA. However, no evidence is given that H3.3 genes of other plants are similarly situated. Consequently, this DNA sequence can be of indeterminate size--large, small or unspecified. Furthermore, no conserved sequences within any alleged length of sequence have been described.

Applicant traverses primarily that the Examiner's excerpts from Sinibaldi are taken out of context even though they teach that "there is variability among different introns, even within the same gene." (Response, p. 8) Applicant says that "the variability that Sinibaldi has remarked upon has not prevented the authors from identifying splice

junctions, to align them, and to identify consensus sequences based on those alignments (from 218 monocot introns and 505 dicot introns).

Applicant's traversal is unpersuasive. There is no indication that the data of Sinibaldi, namely Tables I and II, pages 233-234, came from introns of highly variable distances from the coding sequence. Rather Sinibaldi sets forth data from DNA sequences in which introns had already been identified. No evidence is given that introns could be described given only the information of the splice site consensus sequences of Sinibaldi at the time of filing of the instant case.

Claim Rejections - 35 USC § 112-enablement

9. Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record set forth in the Office Actions mailed 2 July 2004, 18 April 2005 and 18 September 2006.

Applicant traverses that the one of ordinary skill in the art could identify and obtain any 5' intron of a plant H3.3 gene using routine methods...and as further evidenced by the exemplary sequence alignments provided (Response, p. 9) in Attachment A filed 2 November 2004. Applicant further asserts that the fact that the alignments to rice and vine are dated 2003 and 2004 is immaterial (Response, p. 10).

Applicant's traversal is unpersuasive. Applicant's disclosure has provided information on the 5' regions of two H3.3-like histone genes of Arabidopsis, a dicot angiosperm plant. The sequence information for the two examples given, rice and vine, necessary for this determination was available as of February 2004 and May 2003 respectively (see NCBI accessions AAS19511 and AAP307390). *Furthermore*

Applicant is evaluating and analyzing the data and technology of the year 1995 (the date of filing) through the eyes of one of skill in the art as of the year 2004. Applicant has used 2004 technology and information to evaluate scientific data and technology of 1995. The specification must be complete as of the date of filing, whereas the cited information was not available as of the date of earliest filing date of the instant case (19 July 1995).

See In re Glass, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

Applicant further asserts, "it should be noted that under similar circumstances in Capon, supra, the BPAI presumed and the Federal Circuit did not overturn this presumption"(Response, p. 9).

Applicant's traversal is unpersuasive. Regarding *Capon*, the Examiner maintains that different fact patterns are involved in the instant application. In *Capon*, the claims encompassed the well-developed antibody art, wherein "over 785 mouse antibody DNA light chains and 1,327 mouse antibody DNA heavy chains were known and published as early as 1991". In the instant application, Applicant isolated two 5' introns from the H3.3-like gene of a single genomic clone of a single plant species, and no H3.3-like 5' introns from any other genes or plant species were reduced to practice or otherwise known in the art.

Given the sequence divergence of introns as taught by Sinibaldi discussed above, the lack of data from any plant H3.3 histone genes, the lack of information

regarding the size or size range of the 5' region in which the expected 5' intron would occur, undue experimentation would have been required by one skilled in the art to attempt to isolate a multitude of introns from a multitude of non-exemplified plant species as broadly claimed. Furthermore, given the different behavior of introns in monocots versus dicots, undue experimentation would have been required to evaluate the ability of any isolated putative introns to actually function as such in heterologous plant host species.

Remarks

10. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 10-6 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD
Patent Examiner
Art Unit 1638
22 November 2006

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638